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Janssen Research and Development, LLC,
and Cilag GmbH International

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MITSUBISHI TANABE PHARMA
CORPORATION, JANSSEN
PHARMACEUTICALS, INC., JANSSEN
PHARMACEUTICA NV, JANSSEN
RESEARCH AND DEVELOPMENT, LLC, and
CILAG GMBH INTERNATIONAL,

Plaintiffs,

v.

AUROBINDO PHARMA USA, INC.,

Defendant.

Civil Action No. 20-3102 (RMB)(JS)

(Filed Electronically)

CONSENT JUDGMENT AND ORDER

WHEREAS Civil Action No. 20-3102 has been brought by Plaintiffs Mitsubishi Tanabe Pharma Corp., Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, “Plaintiffs”) against Defendant Aurobindo Pharma USA, Inc., (“Aurobindo”) alleging infringement of United States Patent Nos. 7,943,582 (“the ’582 Patent”) and 8,513,202 (“the ’202 Patent”);

WHEREAS Plaintiffs currently market in the United States pursuant to New Drug Application No. 205879 extended-release tablets containing canagliflozin and metformin under the trade name INVOKAMET XR® (the “Invokamet XR Product”);

WHEREAS Aurobindo filed or caused to be filed Abbreviated New Drug Application (“ANDA”) 213900 (the “Aurobindo ANDA”) containing “paragraph IV certifications” with respect to the ’582 and ’202 Patents and seeking FDA approval to make, sell, offer for sale, use and/or import in or for the United States a product asserted to be bioequivalent to the Invokamet XR Product, as described in the Aurobindo ANDA (the “Aurobindo Product”);

WHEREAS Aurobindo admits that the claims of each of the ’582 and ’202 Patents are valid and enforceable with respect to the manufacture, use, sale, offer for sale, and importation of the Aurobindo Product in the United States;

WHEREAS Aurobindo has not, at this time, rebutted the statutory presumption that the ’582 and ’202 Patents are valid and enforceable;

WHEREAS Aurobindo admits that the submission of the Aurobindo ANDA to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of the Aurobindo Product within the United States prior to the expiration of the ’582 and ’202 Patents was a technical act of patent infringement with respect to one or more claims of each of the ’582 and ’202 Patents;

WHEREAS Plaintiffs and Aurobindo have resolved this litigation for good cause and valuable consideration recognized by Plaintiffs and Aurobindo;

WHEREAS Plaintiffs and Aurobindo respectfully request that the Court terminate the pending litigation as between Plaintiffs and Aurobindo by the entry of this Judgment and Order; and

WHEREAS Plaintiffs and Aurobindo now consent to this Judgment and Order. IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. This Court has jurisdiction over the parties and subject matter of this action.
2. The submission of the Aurobindo ANDA to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of the Aurobindo Product within the United States prior to the expiration of the '582 and '202 Patents was a technical act of patent infringement with respect to one or more claims of each of the '582 and '202 Patents under 35 U.S.C. § 271(e)(2)(A).
3. The claims of each of the '582 and '202 Patents are valid and enforceable solely with respect to the manufacture, use, sale, offer for sale, and importation of the Aurobindo Product in the United States.
4. Aurobindo's manufacture, sale, offer for sale, use or import of the Aurobindo Product in the United States would constitute infringement of one or more claims of each of the '582 and '202 Patents absent authorization by Plaintiffs.
5. Aurobindo and its affiliates are hereby enjoined from manufacturing, using, offering for sale, selling in the United States, or importing into the United States, the Aurobindo Product until the expiration of the '582 and '202 Patents, including any patent term extensions

and/or patent term adjustments and during the period of any associated pediatric exclusivity, other than as authorized by Plaintiffs.

6. Neither this Judgment and Order nor the entry of this Judgment and Order may be asserted by Plaintiffs against Aurobindo or any of its affiliates, and shall have no preclusive effect whatsoever, in any cause of action, litigation or proceeding with respect to any product other than the Aurobindo Product in the United States or with respect to any patent other than the '582 and '202 Patents.

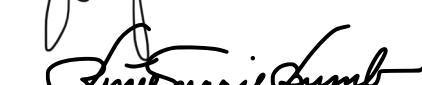
7. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Plaintiffs against Aurobindo and its affiliates, or by Aurobindo and its affiliates against Plaintiffs, in this action solely with respect to the Aurobindo Product and/or the '582 and '202 Patents are hereby dismissed with prejudice.

8. Plaintiffs and Aurobindo shall bear their own fees and costs in connection with this action, including attorneys' fees.

9. Plaintiffs and Aurobindo waive all right to appeal or otherwise move for relief from this Judgment and Order.

10. This Court shall retain jurisdiction of this action and over Plaintiffs and Aurobindo for purposes of enforcement of the provisions of this Judgment and Order.

IT IS SO ORDERED this 17 day of July 2020



HONORABLE RENEE MARIE BUMB
UNITED STATES DISTRICT JUDGE

Dated: May 29, 2020

s/ Charles M. Lizza

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